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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,238	09/16/2003	Alain V. Khaiat	J&J5037CIP1	3755
27777	7590	05/25/2006	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			VU, JAKE MINH	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/663,238	Applicant(s) KHAIAT ET AL.	
	Examiner Jake M. Vu	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-12 and 14-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-12 and 14-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt is acknowledged of Applicant's Amendment filed 03/20/06. Claims 1, 2, 6, 7, 12, 14, 20, 21, 25 and 27 have been amended. Claims 5 and 13 have been cancelled. Claims 1-4, 6-12 and 14-27 are pending in the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 9, 11 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by WALDSTRICHER (US 5,543,417).

Applicant's claims are directed to a method of use and composition comprising of: a 5-alpha-reductase inhibitor; an anti-inflammatory agent, such as allantoin; a keratolytic agent, such as salicylic acid; and a bacterial proliferation inhibitor, such as clindamycin.

WALDSTREICHER disclosed a method of treating acne by applying a composition comprised of: 5-alpha-reductase inhibitor (abstract); an anti-inflammatory agent, such as allantoin (abstract and col. 63, line 56); a keratolytic agent, such as salicylic acid (col. 59, line 12); and a bacterial proliferation inhibitor, such as clindamycin (col. 58, line 59).

Note, the capable of limitation "whereby the appearance of said skin improves within two days of said topical application" is inherent, since the prior art's composition has the same ingredients.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 6, 7, 9-11, 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over WALDSTREICHER (US 5,543,417) in view of DALKO et al (US 6,846,812), and CHAN et al (The analgesic and anti-inflammatory effects of *Portulaca oleracea* L. subsp. *Sativa* (Haw.) Celak. J Ethnopharmacol. 2000 Dec; 73(3):445-51).

Applicant's claims are directed to a method of use and composition comprising of: 5-alpha-reductase inhibitors, such as a glycine; anti-bacterial agents such as clindamycin; keratolytic agents, such as salicylic acid; and anti-inflammatory agents, such as portulaca extract.

WALDSTREICHER disclosed an acne treating composition comprised of: 5-alpha-reductase inhibitors; anti-bacterial agents, such as clindamycin (col. 58, line 59); keratolytic agents, such as salicylic acid (col. 59, line 12); and anti-inflammatory agents.

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WALDSTREICHER does not specifically teach using 5-alpha-reductase inhibitors, such as a glycine or anti-inflammatory agents, such as portulaca extract.

DALKO disclosed a 5-alpha-reductase inhibitor, such as capryloyl glycine, which is a glycine, and cinnamon extract for treating seborrhea and acne (col. 8, line 53-55 and col. 9, line 9-11).

CHAN disclosed an anti-inflammatory agent, such as portulaca extract, which possessed significant anti-inflammatory activities when compared with synthetic drugs (abstract and pg. 446).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate capryloyl glycine, cinnamon extract, and portulaca extracts into WALDSTRICHER' s composition. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because these ingredients are the same type of ingredients used by WALDSTRICHER.

Claims 1-4, 6-12 and 14-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over WALDSTREICHER (US 5,543,417) in view of DALKO et al (US 6,846,812), CHAN et al (The analgesic and anti-inflammatory effects of Portulaca oleracea L. subsp. Sativa (Haw.) Celak. J Ethnopharmacol. 2000 Dec; 73(3):445-51), and SATO et al (US 5,200,429).

As discussed above, WALDSTREICHER disclosed an acne treating composition comprised of: 5-alpha-reductase inhibitors; anti-bacterial agents, such as clindamycin

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(col. 58, line 59); keratolytic agents, such as salicylic acid (col. 59, line 12); and anti-inflammatory agents. DALKO disclosed a 5-alpha-reductase inhibitor, such as capryloyl glycine, which is a glycine, and cinnamon extract for treating seborrhea and acne (col. 8, line 53-55 and col. 9, line 9-11). CHAN disclosed an anti-inflammatory agent, such as portulaca extract, which possessed significant anti-inflammatory activities when compared with synthetic drugs (abstract and pg. 446).

These references do not teach using a bacterial lipase inhibitor such as cedarwood extract.

SATO disclosed using cedarwood extracts for treating acne (col. 2, line 54 and abstract).

These references show that it was well known in the art at the time of the invention to use the claimed ingredients for treating acne. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. In this instance, Applicant's composition is used for treating acne. The idea for combining them flows logically from their having been used individually in the prior art. *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072. MPEP § 2144.06 Art Recognized Equivalence for the Same Purpose.

Based on the disclosure by these references that these substances are used to treat acnes, an artisan of ordinary skill would have a reasonable expectation that a combination of the ingredients would also be useful in creating compositions to treat acnes. Therefore, the artisan would have been motivated to combine the claimed

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ingredients into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See *In re Sussman*, 1943 C.D. 518; *In re Huellmantel* 139 USPQ 496; *In re Crockett* 126 USPQ 186.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

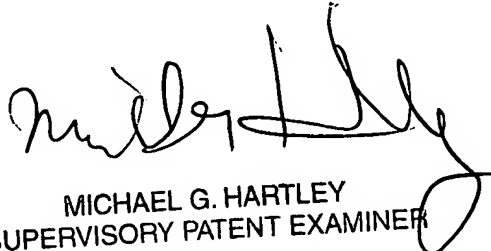
Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jake M. Vu whose telephone number is (571) 272-8148. The examiner can normally be reached on Mon-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jake M. Vu, PharmD, JD
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MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER